PATENT COOPERATION TREATY

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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 14538A-52-1P	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/16722	International filing date *(day/month/year)* 16 JUNE 2000	Priority date *(day/month/year)* 17 JUNE 1999
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant FRED HUTCHINSON CANCER RESEARCH CENTER		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 JANUARY 2001	17 SEPTEMBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GARY JONES Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998) ★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/16722

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-39, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the claims:
pages 40-42, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the drawings:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/16722

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	NONE	YES
	Claims	1-20	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial Applicability (IA)	Claims	NONE	YES
	Claims	1-20	NO

2. citations and explanations (Rule 70.7)

Claims 1-11 lack an inventive step under PCT Article 33(3) as being obvious over Erlich et al. (US 5,541,065) in view of Fodor et al. (US 5,800,992). Claims 1-11 are drawn to a microarray of oligonucleotides said microarray comprising a plurality of HLA Class I oligonucleotide probes on a solid support, said plurality of probes being sufficient to represent at least 80% of known polymorphisms in the HLA Class I locus. Erlich et al. teach a solid support comprising a plurality of HLA Class I oligonucleotide probes said probes being sufficient to represent at least 98% of known polymorphisms in the HLA Class I locus wherein said probes are selected from the HLA-A and HLA-B probes and HLA-B exon 2 probes (Column 10, line 31-Column 11, line 9). Erlich et al. do not teach the solid support is a microarray however, microarrays comprising probes representing polymorphisms were well known and practiced in the art for in the art at the time the claimed invention was made. Specif ically, Fodor et al. teach a microarray comprising a plurality of sequence-specific oligonucleotide probes(Column 2, lines 26-67). It would have been obvious to one of ordinary skill in the art to modify the solid support of Erlich et al. and to attach the HLA-specific probes on a microarray as taught by Fodor et al. for the expected benefit of increased speed, accuracy and reliability of array based microassays as taught by Fodor et al. (Column 2, lines 30-33).

Claims 12-17 lack an inventive step under PCT Article 33(3) as being obvious over Holmes (US 5,541,065) in view of Erlich (US 5.541.065). The claims are drawn to a method of preparing an array of covalently-attached oligonucleotides comprising: . contacting a solid support with an aminoalkyltrialkoxysilane; a linking group; and attaching a plurality of oligonucleotide probes to said linking group to from an array (Column 15, lines 10-64) but they do not teach said probes represent a plurality of polymorphisms . However, Erlich et al. teach the probes representing HLA polymorphisms (Column 10, line 21-Column 11, line 9) wherein the probes are immobilized on a solid support. It would have been obvious to one skilled in the art to immobilize the probes of Erlich et al. on the array support of (Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:
The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): C12Q 1/68; C12P 19/34, C12M 1/36; G01N 16/06 and US Cl.: 435/6, 91.2 287.2; 422/68.1

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):
Holmes for the expected benefit of improved immobilization of the probes of interest as taught by Holmes (Column 2, lines 23-27).

Claims 18-20 lack an inventive step under PCT Article 33(3) as being obvious over Erlich et al. (US 5,541,065). The claims are drawn to methods of HLA tissue typing comprising: amplifying exons 2 and 3 from genomic sample; contacting the amplified product with a microarray and detecting hybridization pattern. Erlich et al. teach the claimed methods for tissue typing (Examples 1 & 2) but they do not teach hybridizing said amplification to a microarray. However, microarrays comprising sequence-specific probes were well known and practiced in the art and it would have been obvious to one skilled in the art to analyze the hybridization of Erlich et al. on a microarray for the known benefits of rapid, accurate and reliable assays analysis.

---------- NEW CITATIONS ----------
US 5,541,065 A (ERLICH et al) 30 July 1996 (30.06.1996), see columns 7-11.